US ERA ARCHIVE DOCUMENT

EFFICACY REVIEW

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FILE OR REG. NO.	4822-UGG
PETITION OR EXP. PERMIT NO	
DATE DIV. RECEIVED	October 17, 1994
DATE OF SUBMISSION	October 10, 1994
DATE SUBMISSION ACCEPTED	
TYPE PRODUCT(S): (I,)D, H, F,	N, R, S <u>Miticide</u>
DATA ACCESSION NO(S). 434124-0	08;D210137;S475984;Case#044988;AC:165
PRODUCT MGR. NO.	10-Johnson/Waldo
PRODUCT NAME(S) RAID #319 Alle	ergen Control Carpet & Room Deodorizer
COMPANY NAME S. C. Jo	hnson & Son, Incorporated
SUBMISSION PURPOSE Provide pe	erformance data in support of claims
for mitici	dal action vs. house dust mites & re-
<u>duction of</u>	allergens in carpet up to 6 weeks.
CHEMICAL & FORMULATION Benzyl (1 5 g/ml	benzoate = 4.6% bulk density crystals, ready-to-use)
CONCLUTIONS & RECOMMENDATIONS The data presented in EPA Accession (MRID) Number 434124-08, having been obtained from laboratory testing corducted according to a company-designed protocol which meets the requirements of § 95-11(b)(1) and (3)-(7) on p. 268 and the standard of § 95-11(c)(2) on p. 270 of the Product Performance Guidelines by substitution of a crystalline powder for a spray, and	
which meets the GLP requirement demonstrate once again the acceptance (which are well known and prescribed following label claims for the to label directions: "(Mitticidal Rug & Room Deodor draft label); the following a ing to eliminate (kill) the claiminate dust mates" in lift and 19; " liminate(s) "eliminatedust mites" in lines 20 and 21 and "co the duration claim in line 20.	ents of 40 CFR 160, are adequate to aricidal properties of benzyl benzoate eviously established) and support the esubject product when used according ticidal Carpet Deodorizer) and/or izer) on the front panel (p. 1 of the caricidal claims on p. 2: "by help-lust mites" in line 3; "helps ene 6; "Kills dust mites." in lines 15, dust mites" in lines 18 and 25 and "in line 22; "Controls dust mites" ontrol dust mites." in line 26. Also, 21 of "up to 4 weeks (30 days) (1 daim " (6 weeks) " (to be continued)

Furthermore, the data in MRID No. 434124-08 relative to establishment and use of an analytical method for determining quanine content as a measure of the levels of dust mite allergens present in or on treated surfaces at certain times following treatment are adequate to support the following label claims with regard to the reduction of allergens as a result of using the subject product: "ALLERGEN CONTROL..." in the product name on p. 1; the following claims on p. 2: "...eliminating allergens..." on line 9; "...it helps eliminate [dust mites and their] allergens... " on lines 11 and 12; "Reduces dust mite allergen levels in the home." on line 23; and "Reduces dust mite allergens up to 80%." on line 27. Most of the other statements on p. 2 are based on factual information and do not require comment here. The information presented in the administrative volume entitled "Management of House Dust Mite Allergy" gives confirming proof that the subject product, when applied according to label rates and directions is as effective in reducing populations of <u>Dermatophagoides</u> <u>pteronyssinus</u> as other products containing benzyl benzoate and in some cases even more effective. Of particular value is the comparison to Acarosan, which was the first product to use this active ingredient for house dust mites and was submitted back in 1988. In one of 2 summaries the subject product was clearly better than Acarosan when both were applied at corresponding label rates, and in the other summary the two products were essentially equal in effectiveness. Based on the bulk density of 1.5 grams per milliliter and a volume of 236.5 ml per cup, the label rate of 1/4 cup per square yard is approximately $59.125 \text{ ml } \times 1.5 \text{ qm/ml} = 88.7 \text{ grams product per square yard or } 26.7\%$ more than the 70 grams per square yard used in testing. This gives additional assurance that the label rate will provide reduction of dust mite populations of both D. pteronyssinus and D. farinae of from 81% to 94% and 91% to 98%, respectively, for up to 6 weeks and an 80% reduction of dust mite allergens, regardless of whether or not the product was broomed in following application to treated Incidentally, the "One 16 oz. container will cover carpeting. about 60 sq. ft." statement on p. 3 is equivalent to 1 pound for about 6.67 square yards, or 453.59243 grams/6.67 = 68 grams per square yard, which is very close to the rate used in testing but may be confusing to the purchaser when trying to determine the rate of application. We recommend these statements as to content and/or application rate be harmonized on final printed labeling. Clearly a pound is a more precise estimation of rate than a 1/4 cup unless the weight of the container is somehow equated to its volume on the label itself, which is an option the registrant may wish to choose.

RL Vern L. McFarland, IRB